California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento CA 95814
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

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HOSPITAL INPATIENT PHARMACY AND PRACTICE SELF-ASSESSMENT

The California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

The Board encourages the pharmacist-in-charge to share the information contained in the self-assessment form with other pharmacists and appropriate pharmacy staff. This shared information will assist the staff in understanding and complying with Pharmacy Law.

The pharmacist-in-charge must also complete a self-assessment within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ **Phone:** _____

Ownership: _____

Permit # _____ **Exp. Date:** _____ **Other Permit #** _____ **Exp. Date:** _____

DEA Permit # _____ **Exp. Date:** _____ **Date of DEA Inventory:** _____

Hours: ***Daily*** _____ ***Sat.*** _____ ***Sun.*** _____ ***24 Hours*** _____

PIC : _____ **RPH #** _____ **Exp. Date:** _____

Staff:

1. _____ **RPH #** _____ **Exp. Date:** _____

2. _____ **RPH #** _____ **Exp. Date:** _____

3. _____ **RPH #** _____ **Exp. Date:** _____

4. _____ **RPH #** _____ **Exp. Date:** _____

Additional pharmacy staff information may be entered on the back of this page. Add separate sheet if necessary.

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, **RPH #** _____, **hereby certify that I have completed the self-assessment of this pharmacy of which I am pharmacist in charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.**

Signature _____ **Date** _____
(Pharmacist-in-Charge)

Additional pharmacy staff (pharmacists or pharmacy technicians) may be listed below:

5. _____ TCH # _____ Exp. Date: _____

6. _____ TCH # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____

8. _____ RPH # _____ Exp. Date: _____

9. _____ RPH # _____ Exp. Date: _____

10. _____ RPH # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

LEGAL REFERENCES used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&PC], Chapter 9, Division 2) can be found in the *California Pharmacy Law.*

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law*.

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

BOARD PUBLICATIONS
(*Intern/Preceptor Manual*
and *Candidate's Review Guide)*
may be obtained by contacting:

Department of General Services
Documents & Publications Section
P.O. Box 1015
North Highlands CA 95660
(916) 574-2200

CALIFORNIA PHARMACY LAW
may be obtained by contacting:

Law Tech
1060 Calle Cordillera, Suite 105
San Clemente CA 92673
(800) 498-0911 Ext. 74
www.lawtech-pub.com

TRIPLICATE FORMS
may be obtained from:

Bureau of Narcotic Enforcement
P.O. Box 161089
Sacramento CA 95816
(916) 227-4050

The DRUG ENFORCEMENT ADMINISTRATION may be contacted at:

DEA
255 East Temple Street, 20th Floor
Los Angeles CA 90012
(213) 894-2216, 2217, 4697, or 6711
(213) 894-4016 (Diversion or Investigation)

DEA
450 Golden Gate Avenue
San Francisco CA 94102
(415) 436-7900
(415) 436-7854 (Theft Reports or Diversion)

DEA
1860 Howe Avenue
Sacramento CA 95825
(916) 566-7160

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

HOSPITAL INPATIENT PHARMACY AND PRACTICE SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO," enter an explanation on "CORRECTIVE ACTION or ACTION PLAN" lines below. If more space is needed, you may add additional sheets.

Yes No N/A

1. Pharmacy

☐ ☐ ☐ The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4117, CCR 1714)

☐ ☐ ☐ The pharmacy maintains "night stock" medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])

☐ ☐ ☐ The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)

☐ ☐ ☐ The pharmacy premises, fixtures and equipment are maintained in a clean and orderly condition. (CCR 1714)

☐ ☐ ☐ The pharmacy sink has hot and cold running water. (CCR 1714)

☐ ☐ ☐ The pharmacy has a readily accessible restroom. (CCR 1714)

☐ ☐ ☐ The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

CORRECTIVE ACTION or ACTION PLAN: _____

_____

a. Compounding Area for Parenteral Solutions (if applicable)

☐ ☐ ☐ The pharmacy has a designated area for the preparation of sterile products that has the following: (if not applicable, check N/A and go to section 2)

☐ ☐ ☐ • A laminar air flow hood or clean room in accordance with Federal Standard 209(b). (CCR 1751[d])

☐ ☐ ☐ • Nonporous and cleanable surfaces including the walls, floors and floor coverings. (CCR 1751[b])

☐ ☐ ☐ • Sufficient space, well separated from the laminar flow hood area, for the storage of bulk materials, equipment and waste materials. (CCR 1751[e])

☐ ☐ ☐ • Ventilation that does not interfere with the laminar air flow. (CCR 1751[c])

☐ ☐ ☐ • A sink with hot and cold running water within the parenteral solution compounding area or adjacent to it. (CCR 1751[f])

Yes No N/A

- A vertical laminar air flow hood in which the preparation of parenteral cytotoxic agents is performed in accordance with section 505.11.1 of Title 24 CCR. (CCR 1751.1)
- Gowns and gloves are worn when preparing cytotoxic agents. (CCR 1751.4)
- Certification of all laminar flow hoods is completed at least annually, and records are maintained on file for at least three years. (CCR 1751[d], 1751.1)
- Current reference materials (relating to the drugs and chemicals used in all parenteral therapy services and all therapy compounding, dispensing, distribution and counseling services provided) are available to the pharmacy. (CCR 1751.9)

CORRECTIVE ACTION or ACTION PLAN: _____

b. Training of Staff, Patient and Caregiver

The pharmacist-in-charge (PIC) is responsible for ensuring that all pharmacy personnel engaging in the compounding of parenteral solutions have training and demonstrated competence in the safe handling and compounding of parenteral solutions including cytotoxic agents and for ensuring their continuing competence. (CCR 1751.5)

Records of training and demonstrated competence for each individual are available and retained for three years beyond each individual's period of employment. (CCR 1751.5)

c. Quality Assurance

The pharmacy has a documented, ongoing quality assurance program that monitors personnel performance, cleaning and sanitization of the parenteral medication preparation area, and proper storage of final compounded parenteral products. (CCR 1751.7)

Written policies and procedures associated with the pharmacy's preparation and furnishing of parenteral products include, but are not limited to: compounding and labeling of intravenous admixtures, administration of intravenous therapy, quality assurance program, recordkeeping requirements, procedures for handling and disposal of infectious materials and/or materials containing cytotoxic residues, and training of staff, patients and caregivers. (CCR 1751.6, 1751.8)

CORRECTIVE ACTION or ACTION PLAN: _____

2. Nursing Stations

Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

The pharmacist is responsible for the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (22 CCR 70263[q][10])

CORRECTIVE ACTION or ACTION PLAN: _____

Yes No N/A

3. Drug Stock

☐ ☐ ☐ The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22 CCR 70263[q])

☐ ☐ ☐ All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. (22 CCR 70263[n])

☐ ☐ ☐ Preferentially priced drugs are furnished solely or predominantly to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales). (B&PC 4380, CCR 1710)

CORRECTIVE ACTION or ACTION PLAN: _____

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4. Pharmacist-in-Charge (PIC)

☐ ☐ ☐ The pharmacy has a PIC who is responsible for the pharmacy's compliance with all state and federal pharmacy laws, and who has knowledge and responsibility of the daily operations of the pharmacy. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐ ☐ ☐ The PIC is PIC at only one pharmacy. Exception: A pharmacist may serve as PIC for two pharmacies if (1) the PIC is the only pharmacist at each pharmacy, and (2) the pharmacies do not have overlapping hours of business. Additionally, the PIC is not serving concurrently as the sole pharmacist for a wholesaler, a medical device retailer or a veterinary food-animal drug retailer. (CCR 1709.1)

CORRECTIVE ACTION or ACTION PLAN: _____

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5. Duties of a Pharmacist

☐ ☐ ☐ Within the scope of the inpatient pharmacy service, the pharmacist: receives a chart order for an inpatient; identifies, evaluates and interprets the chart order; reviews patient's drug regimen and interprets the clinical data in the patient's medication record; consults with any prescriber, nurse or health care professional; calculates drug doses; supervises the packaging of drugs and checks the packaging procedures and products upon completion; is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are performed completely, safely and without risk of harm to patients; performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (B&PC 4051, CCR 1793.1)

☐ ☐ ☐ Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator: ordering or performing routine drug therapy-related patient assessment procedures; ordering drug therapy related laboratory tests; administering drugs or biologicals by injection; initiating or adjusting the drug regimen of a patient; and/or performing moderate or waived laboratory tests. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052(b). (B&PC 4027, 4051, 4052)

CORRECTIVE ACTION or ACTION PLAN: _____

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Yes No N/A

6. Duties of an Intern Pharmacist

☐ ☐ ☐ Intern pharmacists are performing all the functions of a pharmacist **only** under the direct supervision of a pharmacist, and the pharmacist is supervising no more than one intern at any one time. (B&PC 4114, CCR 1726, 1727)

CORRECTIVE ACTION or ACTION PLAN: _____

7. Duties of a Pharmacy Technician

☐ ☐ ☐ Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4038, 4115, CCR 1793.2)

☐ ☐ ☐ The ratio for technicians performing the tasks above, related to the furnishing of drugs to inpatients, does not exceed one pharmacist on duty for two technicians on duty. However, when prescriptions are dispensed to discharge patients, the ratio does not exceed one pharmacist to one technician. (B&PC 4038, 4115, CCR 1793.7[f])

☐ ☐ ☐ Any function performed by a technician in connection with the furnishing of drugs on chart orders and dispensing of prescriptions, including repackaging from bulk and storage of pharmaceuticals, is verified and documented in writing by a pharmacist. (CCR 1793.7)

☐ ☐ ☐ A pharmacy technician wears identification identifying him or herself as a pharmacy technician. (CCR 1793.7)

☐ ☐ ☐ The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with the technician requirements. (CCR 1793.7)

CORRECTIVE ACTION or ACTION PLAN: _____

8. Duties of a Non-Licensed Personnel

☐ ☐ ☐ A nonlicensed person (clerk-typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (CCR 1793.3)

☐ ☐ ☐ The ratio is no more than one pharmacist to one clerk-typist. (B&PC 4115[g], CCR 1793.3)

CORRECTIVE ACTION or ACTION PLAN: _____

PHARMACY PRACTICE

9. Pharmaceutical Service Requirements

The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:

☐ ☐ ☐ • Basic information concerning investigational drugs and adverse drug reactions

☐ ☐ ☐ • Repackaging and compounding records

Yes No N/A

- Physician orders
- Wards, nursing stations and night stock medications
- Drugs brought into the facility by patients for storage or use
- Bedside medications
- Emergency drug supply
- Pass medications
- Inspection of ward stock, nursing stations and night lockers no less frequently than every 30 days
- Outdated drugs
- Routine distribution of inpatient medications
- Preparation, labeling and distribution of IV admixtures and cytotoxic agents
- Handling of medication when pharmacist not on duty
- Use of electronic image and data order transmissions

The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

- Destruction of controlled substances
- Development and maintenance of the hospital's formulary

(22 CCR 70263, CCR 1751, 1751.8)

Drug samples are distributed in compliance with B&PC 4061.

CORRECTIVE ACTION or ACTION PLAN: _____

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10. Medication/Chart Order

The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (B&PC 4019, 4040, CCR 1717.4)

The chart or medical record of the patient contains all of the information required by B&PC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (B&PC 4040, 22 CCR 70263[g])

CORRECTIVE ACTION or ACTION PLAN: _____

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11. Labeling and Distribution

Unit dose medication and parenteral admixtures are properly labeled and include the information as required by B&PC 4076, or the information is otherwise readily available at the time of drug administration. (B&PC 4076)

Yes No N/A

☐☐☐ The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o])

CORRECTIVE ACTION or ACTION PLAN: _____

12. Duration of Drug Therapy

☐☐☐ The hospital has policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. Limitations are established for classes of drugs and/or individual drug entities. (22 CCR 70263[j])

CORRECTIVE ACTION or ACTION PLAN: _____

13. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

☐☐☐ Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

☐☐☐ Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (B&PC 4040, CCR 1764)

☐☐☐ Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

☐☐☐ The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

CORRECTIVE ACTION or ACTION PLAN: _____

14. Recordkeeping Requirements

☐☐☐ A completed biennial pharmacy self-assessment form is on file. (CCR 1715)

☐☐☐ All acquisition and disposition records (complete accountability) are maintained for at least three years. These records include: chart orders, invoices US official order forms—DEA Form-222) (Drug Enforcement Administration), prescription records, power of attorney (21 CFR 1305.07), theft and loss reports (DEA Form-106, 21 CFR 1301.74[c]), and biennial controlled substances inventories (21 CFR 1304.11). (B&PC 4081, 4332, CCR 1718)

☐☐☐ Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21 CFR 1307.11, Prescription Drug Marketing Act of 1987 [PDMA] [Pub.L. 100-293, Apr. 22, 1988] 503, B&PC 4160)

☐☐☐ If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, PDMA 503, B&PC 4160)

Yes No N/A

☐ ☐ ☐ A controlled substances inventory is completed biennially (every two years).
Date completed: _____ (21 CFR 1304.13)

☐ ☐ ☐ Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)

☐ ☐ ☐ Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)

☐ ☐ ☐ DEA Forms-222 are properly executed. (21 CFR 1305.09)

☐ ☐ ☐ When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2s of the DEA Form-222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1309.09)

☐ ☐ ☐ The originals of dispensed official triplicate prescriptions, properly completed, are submitted to the Department of Justice at the end of the month in which the presciption was dispensed. (H&S 11164)

☐ ☐ ☐ Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)

☐ ☐ ☐ Records stored off-site are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Records for controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707)

CORRECTIVE ACTION or ACTION PLAN: _____

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15. After-Hours Supply of Medication

☐ ☐ ☐ The pharmacy maintains a record of the drugs taken from the after-hours supply of medications and the pharmacist is notified of such use. The record includes the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. (22 CCR 70263[n])

CORRECTIVE ACTION or ACTION PLAN: _____

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16. Drug Supplies for Use in Medical Emergencies

☐ ☐ ☐ A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])

☐ ☐ ☐ Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1])

☐ ☐ ☐ The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that the seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (22 CCR 70263[f][2])

☐ ☐ ☐ The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the written policies. Records of the inspection are kept for at least three years. (22 CCR 70263[f][3])

Yes No N/A

CORRECTIVE ACTION or ACTION PLAN: _____

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17. Schedule II-V Controlled Substances Floor Stock Distribution Records

☐☐☐ Records for the distribution of Schedule II-V controlled substances floor stock are open to inspection by authorized officers of the law and are preserved for at least three years from the date of making. (B&PC 4081)

CORRECTIVE ACTION or ACTION PLAN: _____

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18. Emergency Room Dispensing

☐☐☐ The prescription label contains all the required information. (B&PC 4076)

☐☐☐ The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)

☐☐☐ Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ Prescriptions are dispensed in new, senior-adult ease-of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ Patient package inserts are dispensed with all estrogen and progesterone medications. (21 CFR 310.515, 310.516)

CORRECTIVE ACTION or ACTION PLAN: _____

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19. Discharge Medication/Consultation Services

☐☐☐ Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved by the medical staff that ensures that each patient receives the medication consultation. (B&PC 4074, CCR 1707.2)

☐☐☐ Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)

☐☐☐ The prescription label contains all the required information. (B&PC 4076)

☐☐☐ Appropriate drug warnings and auxiliary labels are provided. (B&PC 4074, CCR 1744)

☐☐☐ The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)

☐☐☐ Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (B&PC 4073)

☐☐☐ If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product. (B&PC 4115[f], CCR 1793.7)

Yes	No	N/A	
☐	☐	☐	Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)
☐	☐	☐	Prescriptions are dispensed in new, senior-adult ease-of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 section 4[b], 16 CFR 1700.14, CCR 1717)
☐	☐	☐	Patient package inserts are dispensed with all estrogen and progesterone medications. (21 CFR 310.515, 310.516)

CORRECTIVE ACTION or ACTION PLAN: _____

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